Procedure
Department: HUMAN RESEARCH PROTECTIOS PROGRAM
Policy Number: VI.D.1
Section: Investigator Responsibilities
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Procedure for Certificate of Confidentiality

Procedure:
This procedure describes the responsibility of the Investigator and the Human Research Protections Program (HRPP) when a Certificate of Confidentiality is obtained for a research project.

I. Investigator Responsibilities.
   A. The Investigator will consider applying for a Certificate of Confidentiality when the results of research participation would yield information in one or more of the following categories:
      1. HIV status, AIDS related complications, or other sexually transmitted diseases (STDs);
      2. Information relating to sexual attitudes, preferences, or practices;
      3. Information relating to the use of alcohol, drugs or other addictive products;
      4. Information pertaining to illegal conduct;
      5. Information that if released could reasonably be damaging to an individual’s financial standing, employability, or reputation within the community;
      6. Information that would normally be recorded in a patient’s medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
      7. Information pertaining to an individual’s psychological well-being or mental health;
      8. Information collected that may be considered sensitive in connection with behavioral interventions and epidemiologic studies;
   B. How to apply for the Certificate of Confidentiality.
      2. It must be noted that the issuance of this certificate is up to the discretion of the NIH. If granted, the Certificate provides indefinite protection from compulsory disclosure, such as subpoena for research data.
      3. Applications for a Certificate of Confidentiality should be submitted to the NIH at least three (3) months prior to the date on which enrollment is expected to begin.
   C. The Investigator should notify the IRB that a Certificate of Confidentiality has been requested in the initial IRB submission.
   D. The Investigator must include language describing the Certificate of Confidentiality as well as any voluntary disclosures, in the “Unforeseeable Risk” section of the informed consent document template.
   E. A copy of the IRB approval letter will be forwarded by the Investigator to the agency, in which the certificate was applied, for final review and determination.

II. IRB Committee Responsibilities.
   A. The IRB Reviewer will assure that the proposed research meets regulatory requirements for approval under 45 CFR 46.111, which includes provisions to protect the privacy of participants and confidentiality of data. This IRB determination will include the recommendation of a Certificate of Confidentiality when the proposed research includes sensitive information that may cause harm to the participant as a result of compelling disclosure.
   B. The IRB Reviewer will review the informed consent documents to assure that a description of the Certificate of Confidentiality and any voluntarily, disclosure...
plans by the Investigator are appropriately described. The Reviewer will verify the appropriate template language from the IRB is included in the ICD.

C. If the Investigator has not already applied for a Certificate of Confidentiality, upon its review of the research, the IRB may recommend that an Investigator apply for a Certificate of Confidentiality.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will conduct a pre-review of the proposed research and consider the potential of sensitive information as defined and verify that a request for a Certificate of Confidentiality has been initiated.
   B. The RCA will consult with the IRB Committee Chairperson if the study contains sensitive information for guidance on whether the Investigator should be contacted and advised to initiate the request for a certificate if he or she has not initiated such a request.
   C. The RCA will pre-review the informed consent documents to verify that a description of the Certificate of Confidentiality is included, as well as any planned voluntary disclosures by the Investigator.
   D. The RCA will proceed with procedures for review and approval at the review level in which the study qualifies